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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,745	04/06/2006	Suraj Shivappa Shetty	PC/4-33421A	2533

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,745	SHETTY ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *3-5,9-12 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 6-8, and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-17 are currently pending in the application.

Applicant's election of eplerenone as the aldosterone receptor antagonist, bumetanide as the diuretic, and valsartan as the ARB (i.e. angiotensin receptor blocker) and election of Group I (i.e. pharmaceutical composition or combination) in the reply filed on 02/03/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 3-5, 9-12, and 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Claims 1-2, 6-8, and 13 are examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 6-8, and 13 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Alexander et al. (U.S. 6,653,306 B1) in view of Brater et al. (Kidney International, 1984, Vol. 26, pgs. 183-189).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Alexander et al. teach a combination comprising therapeutically-effective amount of an epoxy-steroidal aldosterone receptor (ALDO) antagonist and a therapeutically-effective amount of an angiotensin II receptor antagonist (ARB) for the treatment of circulatory disorders including cardiovascular disorders such as hypertension, congestive heart failure (CHF), cardiac hypertrophy, cirrhosis and ascites (see abstract, col. 1, lines 10-20, and col. 4, lines 26-33). Alexander et al. also teach that by combination therapy, it is meant that the ARB and the ALDO combined preparation

entails administration of the compounds in a sequential manner (instant claim 13) or in a simultaneous manner in a single capsule or in multiple separate capsules for each antagonist (see col. 4, lines 61-67 and col. 5, lines 1-2). Particularly, Alexander et al. teach that the combination therapy can consist essentially of an ARB, an ALDO, and a diuretic (instant claims 1 and 6-7; see col. 5, lines 10-12 and col. 14, lines 18-26). Preferred ALDO include eplerenone (instant claims 2 and 8; see col.5, table 1). Preferred ARB include valsartan that can be combined with the ALDO (instant claims 2 and 8; see col. 281, claims 17-19).

Alexander et al. however does not specifically teach addition of bumetanide as the diuretic in the composition.

Brater et al. teach the use of bumetanide in congestive heart failure patients (see abstract). Particularly, Brater et al. teach bumetanide is a new loop diuretic which is 40 to 50 times as potent as furosemide, an older diuretic with a twofold shorter elimination half-life (see pg. 183, left col., last paragraph and pg. 188, left col., lines 3-4). Importantly, Brater et al. teach that bumetanide has a two-fold greater bioavailability as compared to the older diuretic furosemide in normal and congestive heart failure patients though a delayed rate of absorption was observed in congestive heart failure patients (see pg. 183, left col., last paragraph, pg. 187, right col., top paragraph, and pg. 188, left col., lines 18-22).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add the bumetanide of Brater et al. into the combined composition of Alexander et al. since Brater et al. teach that bumetanide is more 40-50 more potent than older diuretics. Moreover, at the time of Applicant's invention, it would have been obvious to one of ordinary skill in the art to include a label and packaging in the combined composition of Alexander and Brater et al. One of ordinary skill in the art would have been motivated to include the packaging and the insert, because it is mandated by law.

Further, it is well-settled law that combining printed instructions and an old product into a kit will not render the claimed invention non-obvious even if the instructions detail a new use for the product. *See In re Negai, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1862 (Fed. Cir. 2004*). Further, the inclusion of a package insert or label showing "the name of drug, dosage form, route of administration, indication and direction of use" of a pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art.

Thus, given the teachings of Alexander and Brater, one of ordinary skill would have been motivated to add bumetanide into the combined preparation/kit of Alexander et al. with the reasonable expectation of providing a combination that is effective in treating circulatory disorders including congestive heart failure and a combination that is highly bioavailable.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

04/25/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617